

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NOVARTIS PHARMACEUTICALS CORPORATION,)	
)	
Plaintiff,)	CONS. C.A. NO. 18-1043-LPS
)	
v.)	(18-1038-LPS)
)	
APOTEX INC. and APOTEX CORP.,)	
)	
Defendants.)	
)	
)	
)	
)	

**STIPULATION AND PROPOSED ORDER
TO STAY BETWEEN PLAINTIFF AND APOTEX**

WHEREAS, on July 13, 2018, Plaintiff Novartis Pharmaceuticals Corporation (“Plaintiff”) commenced Civil Action No. 18-1038-LPS (the “Action”) against Defendants Apotex Inc. and Apotex Corp. (“Apotex”), alleging infringement of U.S. Patent No. 9,187,405 (“the ’405 patent”) based on Apotex’s submission of Abbreviated New Drug Application (“ANDA”) No. 207993 for fingolimod 0.5 mg capsules;

WHEREAS, on February 3, 2017, Apotex brought an *inter-partes* review challenging the validity of the claims of the ’405 patent before the Patent Trials and Appeals Board;

WHEREAS, the Patent Trial and Appeal Board (“PTAB”) instituted Case No. IPR2017-00854 and issued a final written decision denying all three grounds of invalidity;

WHEREAS, Apotex has appealed the decision in Case No. IPR2017-00854 and that appeal is currently pending before the United States Court of Appeals for the Federal Circuit;

WHEREAS, Apotex challenges the validity and enforceability of the ’405 patent before this Court, and therefore denies the disputed allegations in the Action;

WHEREAS, Plaintiff has asserted the ’405 patent against other entities under 35 U.S.C. § 271(e)(2) in related litigations currently pending before this Court, *i.e.*, *Novartis*

Pharmaceuticals Corp. v. Teva Pharmaceuticals USA, Inc. et al., C.A. No. 18-cv-01039-LPS; *Novartis Pharmaceuticals Corp. v. Accord Healthcare Inc. et al.*, C.A. No. 18-cv-01043-LPS, and *Novartis Pharmaceuticals Corp. v. Sun Pharmaceutical Industries, Ltd. et al.*, C.A. No. 18-cv-01040-LPS (collectively, the “Related Actions”);

WHEREAS, on October 25, 2018, the Court consolidated this Action with the Related Actions for all pre-trial purposes, and the lead case is 18-cv-1043-LPS (collectively, the “Consolidated Action”); and

WHEREAS, to conserve the Parties’ and the Court’s resources, time, and expenses, Plaintiff and Apotex have agreed to stay all claims, defenses and/or counterclaims between them.

IT IS HEREBY STIPULATED, subject to the approval of the Court:

1. Except to the extent necessary to implement or enforce this Stipulation and Order, all claims, defenses and/or counterclaims between Plaintiff and Apotex are stayed. This order shall not apply as against any other defendant.

2. Apotex challenges the validity and enforceability of the claims of the ’405 patent but does not contest that the filing of ANDA No. 207993 constitutes an act of infringement under 35 U.S.C. § 271(e)(2) with respect to the asserted claims. Apotex and any affiliates, parents, subsidiaries, or assigns shall be bound by the adjudication on the merits by this District Court in the Consolidated Action regarding the validity, patentability, or unenforceability of the ’405 patent. Upon entry of the last final judgment in the Consolidated Action, this stay shall be lifted, and final judgment shall be entered as between Plaintiff and Apotex as if Apotex had fully participated in the adjudication of the claims and defenses alleged in the Consolidated Action regarding the validity, patentability, or unenforceability of the ’405 patent. Any judgment or determination finding willful infringement and/or exceptional case under 35 U.S.C. § 285, costs under 28 U.S.C. § 1920, or any other award of fees, costs or sanctions in the Consolidated Action shall not be entered or otherwise apply as between Plaintiff and Apotex.

3. Apotex agrees that it will not sell, offer for sale, market, or in any way act on

approval or tentative approval from the FDA for the product that is the subject of Apotex's ANDA No. 207993 unless and until the claims of the '405 patent asserted in the Consolidated Action are found invalid, unpatentable, or unenforceable in a final written opinion or order issued by a district court, the PTAB or the Court of Appeals for the Federal Circuit.

4. If for any reason there is or will be no adjudication on the merits in the Consolidated Action regarding the validity, patentability, or unenforceability of the '405 patent, then either Party may move to lift the stay between Plaintiff and Apotex, provided that neither Plaintiff nor Apotex will seek to lift the stay unless and until Plaintiff and Apotex have first negotiated in good faith at least sixty (60) days prior to the filing of such motion as to how the claims, defenses and/or counterclaims between Plaintiff and Apotex should proceed.

5. If the stay is lifted pursuant to Paragraph 4, the Parties agree to expedite discovery and the case schedule to the extent reasonably practicable.

Dated: November 5, 2018

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

Michael P. Kelly (#2295)
Daniel M. Silver (#4758)
Benjamin A. Smyth (#5528)
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, DE 19801
(302) 984-6300
mkelly@mccarter.com
dsilver@mccarter.com
bsmyth@mccarter.com

Attorneys for Novartis Pharmaceuticals Corporation

POTTER ANDERSON & CORROON LLP

/s/ Bindu A. Palapura

David E. Moore (#3983)
Bindu A. Palapura (#5370)
Hercules Plaza, 6th Floor
1313 N. Market Street
Wilmington, DE 19801
Tel: (302) 984-6000
dmoore@potteranderson.com
bpalapura@potteranderson.com

*Attorneys for Defendant
Apotex Pharmaceuticals Inc. and Apotex Inc.*

OF COUNSEL:

Jane M. Love
Robert Trenchard
Paul E. Torchia
GIBSON, DUNN & CRUTCHER LLP
200 Park Avenue
New York, NY 10166
(212) 351-4000
JLove@gibsondunn.com
RTrenchard@gibsondunn.com
PTorchia@gibsondunn.com

Andrew P. Blythe
GIBSON, DUNN & CRUTCHER LLP
333 South Grand Avenue
Los Angeles, CA 90071
(213) 229-7000
ABlythe@gibsondunn.com

Attorneys for Novartis Pharmaceuticals Corporation

OF COUNSEL:

Tung-On Kong
WILSON SONSINI GOODRICH & ROSATI
One Market - Spear Tower Suite 3300
San Francisco, CA 94105
Tel: (415) 947-2053
tkong@wsgr.com

Dennis Gregory
WILSON SONSINI GOODRICH & ROSATI
1301 Avenue of the Americas
New York, New York 10019
Tel: (212) 999-5800
dgregory@wsgr.com

Mary Procaccio-Flowers
WILSON SONSINI GOODRICH & ROSATI
650 Page Mill Rd.
Palo Alto, California 94304
Tel: (650) 493-9300
mprocaccioflowers@wsgr.com

Diyang Liu
WILSON SONSINI GOODRICH & ROSATI
900 South Capital of Texas Highway
Las Cimas IV, Fifth Floor
Austin, TX 78746
Tel: 512-338-5403
diyang.liu@wsgr.com

Attorneys for Apotex Inc. and Apotex Corp.

IT IS SO ORDERED this _____ day of November, 2018.

Chief United States District Judge
Hon. Leonard P. Stark